

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation,	)	
	)	
	)	
Plaintiff,	)	C. A. No. 05-590
	)	
v.	)	Honorable Gregory M. Sleet
	)	
DEXCOM, INC., a Delaware corporation,	)	
	)	
	)	
Defendant.	)	
_____	)	

**DECLARATION OF TIMOTHY GOODNOW**

1. My name is Timothy Goodnow and I am over 18 years of age. If called upon, I could testify to the truth of the following facts based on my personal knowledge and experience, as well as my understanding of the status of DexCom, Inc.'s efforts to obtain FDA approval of its STS glucose-monitoring device based on publicly-available information.

2. I am an employee of Abbott Diabetes Care, Inc. and my current title is Divisional Vice President for Research and Development.

3. As Divisional Vice President for Research and Development, I oversee and help develop products before they are placed on the market. It is my responsibility to help bring products to market and, in the process, I assist and help oversee efforts to obtain FDA approval for marketing.

4. Over the course of my twenty-year career, I have been involved in dozens of applications for premarket approval from the FDA. My involvement has included developing and gathering relevant information for submission to the FDA, designing and conducting clinical

studies, drafting sections of PMA applications, working closely with the regulatory affairs department, participating in FDA audits, communicating directly with the FDA, and participating in milestone meetings such as 100-day meetings and panel hearings.

5. For the purpose of this declaration, I have been asked to comment on the status of DexCom's efforts to obtain FDA approval for its STS glucose-monitoring device. DexCom reportedly has completed every step of the application process, including clinical trials, quality system audits, BIMO audits, and the pivotal 100-day meeting with the FDA. DexCom is now in a position where the next communication from the FDA could very well be the approval of its product. In fact, I am aware that DexCom has stated that it expects approval in the second quarter of 2006.

6. I know of no reason to doubt that DexCom will obtain FDA approval in the near future. In fact, I believe approval is a foregone conclusion, in part, because DexCom reportedly is seeking approval for its device as a supplement to existing glucose-monitoring products (referred to as an adjunct application).

7. Obtaining adjunct approval from the FDA is less rigorous than obtaining replacement approval. For example, there are fewer regulatory hurdles to overcome. For replacement approval, a company must participate in an FDA panel hearing after successfully completing the 100-day meeting. For adjunct approval, in contrast, the panel hearing is not mandatory under the FDA regulations.

8. Moreover, obtaining adjunct approval inherently means that DexCom's device would act as a "back-up" or a "supplement" to the finger-prick method of glucose monitoring that has been long established as safe, effective, and reliable. In contrast, a replacement device would not be a back-up system and, thus, must be proven to be safe and effective as the sole

method of glucose monitoring.

9. Unlike DexCom, Abbott is not seeking adjunct approval of its own glucose-monitoring product, the Navigator. Instead, it is seeking only replacement approval. There is no question that, as a practical matter, adjunct approval is easier to obtain than replacement approval. When a company seeks both kinds of approval, the FDA often approves the product as an adjunct therapy or device while withholding replacement approval for further review. For the Navigator, Abbott could already have obtained FDA approval if, like DexCom, it was willing to accept mere adjunct approval.

10. In addition to its decision to pursue adjunct approval, DexCom's descriptions of its communications with the FDA indicate that its approval is imminent. DexCom filed its PMA in March of 2005.

11. DexCom achieved its first milestone in May 2005 by convincing the FDA to grant expedited review status for its PMA. That means that the FDA has placed DexCom's application for approval before other applications that are not being reviewed on an expedited basis. It also means that, as necessary, the FDA will devote more resources to review DexCom's application in order to approve it more quickly than other non-expedited applications.

12. The second major milestone that DexCom achieved was successfully completing audits called "BIMO" and "QSR" audits. A BIMO audit is an audit of the collection and quality of clinical trials. A QSR audit, formerly known as a good manufacturing process audit, is an evaluation of the manufacturing process. Through these audits, the FDA evaluated whether the plant where DexCom plans to manufacture its device is acceptable and meets quality control requirements. DexCom reportedly passed both of these audits.

13. Passing the audits is key because it means that as soon as DexCom gets official

approval from the FDA, it can begin manufacturing its product. There will be no delay. Achieving this milestone is also an indication that the FDA will not ask DexCom to change its product. If it was going to ask DexCom to change its product, the FDA would not have approved the facilities to manufacture the product because any such changes would result in a change to the manufacturing process, which would then require further audits. If DexCom were to make a material change, it would have to file a PMA Amendment, which would be disclosed in its SEC filings.

14. The final milestone that DexCom achieved is completion of the 100-day meeting with the FDA. This is a meeting in which the FDA identifies all of the additional information that will be required from an applicant and where the FDA typically indicates when an applicant can expect approval. DexCom publicly announced that all of the FDA's questions are easily answered and, as of September 12, 2005, already comprehensively answered those questions. Based on DexCom's own press releases, no request for information from the FDA remains outstanding.


15. Significantly, again based on DexCom's press releases, the FDA did not ask DexCom to conduct any further clinical trials at the 100-day meeting and also did not suggest that any changes to DexCom's product would be necessary. In my experience, if it believes that additional clinical studies and/or product changes are necessary, the FDA will make these requests at the 100-day meeting or, at least, indicate that the issues are under consideration. Because the FDA made no such requests at DexCom's 100-day meeting, there is no reason to believe that more clinical trials and/or product changes will be required.

16. I understand that DexCom has asserted that it cannot reliably predict whether it will obtain FDA approval. That is contrary to my experience. Based on 100-day meetings with

the FDA, it is usually possible to determine whether approval is to be expected or in jeopardy. That is, after all, one of the primary purposes of the meeting, i.e., to let the company know whether there are any significant obstacles to obtaining approval. Based on DexCom's own press releases, it seems clear that FDA approval is imminent.

17. This is especially true considering that its manufacturing facilities have been approved. With the successful completion of the 100-day meeting and BIMO and QSR audits, there are no other material milestones that DexCom must complete to obtain approval. Accordingly, there is little doubt that DexCom will have a product on the market soon.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct

  
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Timothy Goodnow

CHI:1595448.2

CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2005, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

Steven J. Balick  
ASHBY & GEDDES  
222 Delaware Avenue  
P.O. Box 1150  
Wilmington, DE 19899

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on September 22, 2005 upon the following individuals in the manner indicated:

**BY HAND**

Steven J. Balick  
ASHBY & GEDDES  
222 Delaware Avenue  
P.O. Box 1150  
Wilmington, DE 19899

**BY EMAIL AND FEDERAL EXPRESS**

David C. Doyle  
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3811 Valley Centre Drive  
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*/s/ James W. Parrett, Jr.*

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James W. Parrett, Jr. (#4292)